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EXAMINER
STANTON, B

ART UNIT	PAPER NUMBER
1804	13

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GARY E PARKER
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DATE MAILED: 05/21/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 3/12/95 ☐ This action is made final

A shortened statutory period for response to this action is set to expire THREE (3) month(s), ~~6~~ days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-29 ROMAIN are pending in the application

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-29 STAND AD are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

The amendment filed 5/12/95 (Paper No. 10) and the declarations submitted under 37 C.F.R. § 1.132 executed by Gerald W. Lasser and Donna E. Prunkard (the Lasser and Prunkard declarations, respectively) have been entered. These declarations have been considered as indicated hereinbelow.

Claims 1-29 remain pending in the instant Application.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The outstanding objection to the specification wherein it was indicated that the specification fails to provide an enabling disclosure for any embodiments of what is claimed is hereby withdrawn. However, it is maintained that the specification fails to provide an enabling disclosure for the full scope of what is claimed. Therefore, the outstanding grounds of objection to the specification and corresponding rejection of the claims under 35 U.S.C. § 112, first paragraph, has been restated as indicated hereinbelow. This is the same grounds of objection/rejection as advanced in the preceding Office Action mailed 2/6/95 (Paper No. 9).

Claims 2, 12, and 17 stand rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to mammals and those species of mammals that have been specifically enabled by the prior art for the preparation of transgenic animals that express transgene constructs in their milk. See M.P.E.P. §§ 706.03(n) and 706.03(z). Applicant's arguments filed 5/12/95 (Paper No. 10) have been fully considered but they are not deemed to be persuasive regarding this restated grounds of rejection.

It is maintained that the specification fails to provide an enabling disclosure for the preparation of any and all transgenic animals because the teachings present in the specification are limited to guidance in regard to how one would have transgenic mice and sheep and the artisan would have been required to have exercised undue experimentation in the preparation and use of animals that were not enabled either by the prior art or by teachings present in the instant specification. Thus, generic claims drawn to mammals, while encompassing inoperative embodiments are not precluded from issue. However, claims to and reciting particular embodiments of the invention that would not have been considered to have been enabled by those skilled in the art fail to comply with the requirements of 35

U.S.C. § 112, first paragraph. In this regard, it is noted that claims 2, 12, and 17 recite methods that required transgenic cattle. However, the state of the art at the time of the claimed invention and ensuing after the time of the invention indicate that the artisan would not have accepted, *a priori*, that one could have produced fibrinogen in transgenic cattle as required by the instantly pending claims. For example, a 1994 reference by Houdebine (Y) indicates that transgene expression in milk had not been observed in cattle (see e.g. Tables 4-6) and that regulatory sequences must be tested empirically, leading to unpredictable success and failure (page 274, paragraph bridging columns 1 and 2). Even post-filing, the artisan was unable to predictably use transgenic cattle. For example, a 1996 manuscript by Wall (X) states on page 62, first paragraph that "...transgene expression and the physiological consequences of transgene products in livestock are not always accurately predicted in transgenic mouse studies". Wall further states on page 62, third paragraph, lines 8-10, that "(c)urrently, the only approach that yields truly informative data is testing transgenes in livestock of interest". Thus, based upon the unpredictable nature of the transgene expression art and the particular inoperability in the production of transgenic cattle, it is maintained that the artisan would not have been able to have practiced the methods as required for the inventions as claimed by claims 2, 12, and 17 without having had to have exercised undue experimentation.

Applicant argues that they have provided a variety of examples and teachings that would have enabled the artisan to have practiced the full scope of what is claimed and that those embodiments that are not specifically enabled by the as-filed specification would have been enabled by the prior art as interpreted by the skilled artisan. However, given the nature of what is claimed and the difficulties in preparing transgenic cattle, it is maintained that the preparation of the transgenic cattle required for the practice of the claimed invention would have required undue experimentation.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-8 and 11-29 stand rejected under 35 U.S.C. § 103 as being unpatentable over Meade et al., 1989 (A), Archibald et al., 1990 (A4), and Roy et al., 1991 (A7) for reasons of record advanced in the preceding Office Action mailed 2/6/95 (Paper No. 9). Applicant's arguments filed 5/12/95 (Paper No. 10) have been fully considered but they are not deemed to be persuasive.

Applicant argues that they have been able to have prepared biocompetent fibrinogen and that such production would have been expected. In response, it is noted that the as-pending claims do not recite the preparation of such biocompetent fibrinogen and based on the use of animals as bioreactors and in the absence of any requirement for any particular functionality of recited fibrinogen, it is maintained that the claimed invention would have been *prima facie* obvious.

Applicant has submitted declarations under 37 C.F.R. 1.132 executed by Gerald W. Lasser and Donna E. Plunkard. These declarations evidence the production of biocompetent fibrinogen in transgenic mice. However, as the claims do not recite the nature of the fibrinogen produced in the transgenic animals, these declarations fail to support any unexpected results that are concordant with the as-claimed invention.

Applicant is advised that revision of the claims to recite the production of "biocompetent" fibrinogen would overcome the outstanding grounds of rejection under 35 U.S.C. § 103.

Claims 9 and 10 stand rejected under 35 U.S.C. § 103 as being unpatentable over Meade et al., 1989 (A), Archibald et al., 1990 (A4), and Roy et al., 1991 (A7) as applied to claims 1-8 and 11-29 above, and further in view of Chung et al., 1990 (A18) and Lewin, 1983 (R) for reasons of record advanced in the preceding Office Action mailed 2/6/95 (Paper No. 9). Applicant's arguments filed 5/12/95 (Paper No. 10) have been fully considered but they are not deemed to be persuasive.

Applicant's arguments have been fully addressed above in the rebuttal of the arguments advanced against the preceding grounds of rejection under 35 U.S.C. § 103.

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Stanton whose telephone number is (703) 308-2801. The examiner can normally be reached on Monday through Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Stone can be reached on (703) 308-3153. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1096.

Brian R. Stanton, Ph.D.
21 May 1996

BRIAN R. STANTON
PATENT EXAMINER
GROUP 1800